DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 23 1998

The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Dingell:

This is in further response to your letter of December 3, 1997, in which you submitted fifteen questions regarding imported foods. Enclosed please find our responses to questions 2, 3, 4, 5, 6, 7, 8, 9, 10, and 12(b). This completes our response to your questions.

We appreciate your interest in food safety issues. Please contact us if we may be of further assistance.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosures

cc: The Honorable Thomas J. Bliley, Jr.
Chairman, Committee on Commerce

RESPONSES FROM THE FOOD AND DRUG ADMINISTRATION TO QUESTIONS IN THE DECEMBER 3, 1997 LETTER FROM THE HONORABLE JOHN D. DINGELL, RANKING MEMBER, COMMITTEE ON COMMERCE

2(a) How many shipments of fresh fruits and vegetables imported into the United States has FDA identified in each of the past seven years as having microbial, viral, or parasitic contamination?

2(b) What were the ten countries with the highest incidence of microbial, viral, or parasitic contaminated fresh fruit and vegetable shipments to the United States in each of the past seven years?

Because microbial contamination of imported foods has not been a significant problem, the Food and Drug Administration (FDA or the Agency) has not devoted a significant amount of its limited resources to surveillance for microbial hazards in fresh produce. FDA's efforts regarding microbial problems have been focused on produce identified from tracebacks of foodborne disease outbreaks and/or surveillance information which target specific regions or countries.

Over the past seven years, FDA sampling has identified two imported products as microbially contaminated. These products were fresh melons from Mexico for Salmonella in Fiscal Year (FY) 91 and Mexican green onions for Shigella (high coliforms) identified in FY95.

In recent years, FDA and other Federal agencies have observed an increase in the number of produce-related foodborne outbreaks in the United States. For example, within the past two years, over 2100 cases of illness were epidemiologically linked to Cyclospora-contaminated raspberries from Guatemala. In addition, cases of Salmonella infections were linked to cantaloupe from Mexico in 1991; in 1995, outbreaks of Salmonella occurred in 23 states that were subsequently traced to alfalfa sprout seeds from a Dutch shipper.

When information does become available suggesting that fresh produce imported from any given area may be contaminated with a particular pathogen, FDA will initiate appropriate action to prevent contaminated food from reaching consumers. For example, FDA issues import alerts and sampling assignments to the district offices when problems with imported products are identified. Additional examples of sampling assignments include the sampling of imported fresh produce for Vibrio cholerae from Peru and Mexico in FY91 and from Central America

in FY92, and, more recently, the sampling of Guatemalan raspberries and Peruvian lettuce for Cyclospora in FY96 and FY97.

The sporadic nature of microbial, viral, and parasitic contamination and the difficulty in detecting these contaminants are of great concern to FDA. Of critical importance are the prevention and intervention strategies being developed as part of the President's Food Safety Initiative, namely research and guidance in the form of Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs), which focus on preventing contamination during production and transportation. The successful implementation of these preventive practices will improve food safety and reduce the need to rely on resource intensive product testing.

3. Are there tolerances for microbial, viral, and parasitic contamination of fresh fruits and vegetables, and if not, what is being done by FDA or other federal agencies to develop such tolerances?

Currently, the tolerance level for pathogens in ready-to-eat food, including fresh fruits and vegetables, is zero. In order to establish a different tolerance for any pathogen, the safe level (or infectious dose) must be known. At the present time, no such data exist. In the absence of specific tolerances, regulatory actions, including detention of goods offered for import and seizure of goods in domestic commerce, have been taken under the general adulteration provisions of the Federal Food, Drug, and Cosmetic (FDC) Act against contaminated foods that may pose a risk to public health. Such actions are taken on a case-by-case basis and are based upon a scientific showing by FDA that the contaminated food may pose a risk to the public health.

The legal requirements for establishing a formal tolerance are that the risk factors for a contaminant must be well understood scientifically and that factors affecting the presence of the contaminant in food, i.e., its avoidability or unavoidability, be well understood scientifically. In addition, validated methods must be available to identify and determine the level of the contaminant. The developing science concerning: 1) the microbial contamination of fresh produce; 2) the health risks posed by those contaminants; and 3) the avoidability/ unavoidability of microbial contaminants in foods, makes it unlikely that the Agency could establish tolerances for such contaminants at this time. Even if the state of the science were more definitive, the resource requirements and potential delays in the process to establish tolerances would be considerations in any decision to establish tolerances for

microbial contaminants in fresh fruits and vegetables. While FDA does not rule out establishing such tolerances in the future, we believe that prevention-based strategies focusing on agricultural and food handling practices, as delineated in the Food Safety Initiative and the Produce Initiative, are more efficient and effective at achieving our objective of minimizing microbial risks in fresh fruits and vegetables and ensuring a safe supply of these foods.

4. In recent years, foodborne illness and death has been caused by E. coli contaminated carrots from Peru, Cyclospora-contaminated raspberries from Guatemala, and hepatitis contaminated strawberries from Mexico. What enforcement actions has the FDA taken against the growers and countries that shipped these contaminated fruits and vegetables to the United States?

As a point of clarification, the FDC Act authorizes FDA to prevent the importation of foods that appear to be adulterated. We have no authority over a foreign country or grower, only over products from that country or grower presented for importation. Using this authority, FDA can prevent the importation of problem products, by country or by grower, until the importer shows them to be safe.

As you know, the contaminated frozen strawberries were recalled from the market, and the importer has ceased operation. Guatemala voluntarily has ceased shipments to the United States during the season that has been associated with Cyclospora outbreaks. We believe the report of E. coli illnesses due to Peruvian carrots is erroneous, as explained below.

Infections with enterotoxigenic are a frequent cause of diarrhea in developing countries but not in the United States and other industrialized countries. In 1993, however, there were two foodborne enterotoxigenic E. coli outbreaks that occurred in the United States. One was associated with a garden salad (shredded carrots and three different types of lettuce). The other outbreak was associated with the consumption of a tabouleh salad (carrots, a variety other vegetables, bulgur wheat, spices). All the ingredients were identified as being of United States origin with carrots being the only common ingredient. FDA traceback did not identify a single source for the carrots.

Current science demonstrates that cyclosporiasis is a seasonal illness. Fresh raspberries from Guatemala were epidemiologically implicated by the Centers for Disease Control and Prevention (CDC) as the cause of cyclosporiasis outbreaks in the spring/summer of 1996 and 1997. No deaths were reported

from the 1996 and 1997 outbreaks. In response to these outbreaks, FDA issued assignments to collect and analyze samples of imported Guatemalan raspberries for Cyclospora. FDA did not take enforcement action against fresh Guatemalan raspberries in 1996 or 1997 for several reasons: (1) sampling and analysis failed to identify any shipments as positive for Cyclospora; (2) in 1996, the spring growing season ended about the same time as the CDC epidemiological investigation implicated Guatemalan raspberries; and (3) in 1997, the Guatemalan Berry Commission voluntarily stopped exporting fresh raspberries to the United States between May 30 and August 15, 1997.

On November 20, 1997, FDA's Center for Food Safety and Applied Nutrition notified the President of the Guatemalan Berry Commission that FDA will not allow fresh raspberries entry into the United States during the period of March 15 through August 15, 1998, and that FDA's position may change if the source of Cyclospora contamination is identified and corrected or if intervention technologies are developed which will prevent cyclosporiasis in humans.

Strawberries grown in Mexico and processed and frozen in the United States in 1996 were identified by CDC as being associated with an outbreak of hepatitis A in the United States in 1997. As part of our 1997 follow-up investigation, FDA visited three of four Mexican strawberry growers who had been identified as having shipped strawberries to the United States processor in California for processing and freezing in 1996. FDA's investigation did not develop any evidence that linked the harvest or processing practices of the Mexican growers to the adulteration of strawberries with hepatitis A. The source of the hepatitis A contamination has not been established. Contamination could have occurred in either Mexico or the United States.

5. The Food, Drug, and Cosmetic Act prohibits adulterated food from moving in interstate commerce.

5(a) Does the FDA consider fresh fruits and vegetables to be adulterated if they are imported into the United States with microbial, viral, or parasitic contaminants?

FDA considers adulterated any food product that contains a microbial, viral, or parasitic pathogen that may cause the product to be injurious to health. This policy applies equally to foods offered for import and domestically produced foods. Imports that appear to be adulterated are detained; future shipments from the same source also may be detained without

physical examination until the country, grower, shipper, or importer can establish that the shipment is not adulterated.

5(b) If fresh fruits and vegetables were to be detected as being adulterated upon their importation, does the Food, Drug, and Cosmetic Act provide adequate authority for the FDA to stop their movement in interstate commerce, and, if not, what additional authority is needed?

The controls provided by the FDC Act (e.g., detentions, detention without physical examination, seizures, and recently granted limited civil money penalties for pesticide residue violations) provide FDA with substantial authority to control the movement in interstate commerce of imported foods that are determined to be adulterated.

FDA, however, has neither the authority to maintain physical custody of imported foods until their admissibility has been determined nor, as a practical matter, the physical facilities to do so. Current law and regulations allow an importer to take possession of its merchandise pending completion of FDA's examination. Although formal entries (value greater than $1250) are subject to a Customs entry bond and may be assessed liquidated damages of up to three times their value if improperly distributed, Customs currently does not require a bond for informal entries (value below $1250). Thus, there is no incentive for importers to postpone the distribution of goods that are part of an informal entry. Even in the case of bonded entries, liquidated damages are assessed based upon the foreign cost of the product which may be considerably less than its retail value in the United States, and an importer is often able to inflate the selling price to cover the liquidated damages as a cost of doing business.

The effectiveness and deterrent function of the Act's import provisions could possibly be enhanced if the Agency had the authority: to assess civil penalties for violations (other than pesticide residue violations), to embargo, to mandate the recall of violative food imports, and to inspect records.

6. The Administration's new initiative to ensure the safety of imported and domestic fruits and vegetables would expand the number of FDA inspectors to inspect and monitor growers in foreign countries.

6(a) How many FDA inspectors currently inspect and monitor growers in foreign countries?

6(b) In which countries are inspections conducted?

6(c) How many times in each of the last 4 years have such foreign inspections been carried out?

6(d) How many growers were inspected by FDA over this four year period?

No FDA inspectors currently inspect or monitor produce growers in foreign countries. The new legislative authority proposed by the Administration would give FDA authority to deny entry to foods from countries that do not provide protections equivalent to that of the United States products. In order to enforce this authority, FDA would need additional inspectors to conduct foreign inspections.

FDA's international food inspection program is currently focused on inspections of manufacturers of low acid canned foods and infant formula who have registered with FDA or who offer products for import into the United States. However, there are a variety of non-inspectional activities (in addition to our import controls) that are carried out by FDA to ensure the safety of fruits and vegetables offered for entry into the United States.

Examples of these activities include:

Canada: FDA's district offices along the Canadian border enjoy a close working relationship with counterparts in the Canadian Food Inspection Agency (CFIA) (formerly Health Canada, Canada Agriculture and Fisheries and Oceans), and this relationship has paid tangible results over the years. While we do not inspect Canadian firms/growers, we do advise and work with CFIA officials when violations are detected in Canadian products.

In 1996, FDA detected violative levels of omethoate in blueberries grown in British Columbia. Health Canada and Canada Agriculture were advised and conducted a joint investigation which led to their identification of the grower involved. In addition, those two agencies provided laboratory results certifying that subsequent shipments coming to the United States were not adulterated.

In 1994, FDA detected the pesticides chlorothalonil and captan in currants shipped by two Canadian processors. Health Canada was advised and worked with Canada Agriculture to identify the growers involved and prevented further distribution of the product to the United States and in Canada.

In 1993, FDA's Seattle District Office detained shipments of Canadian apples containing an unapproved fungicide. Health Canada was informed and its follow-up revealed the Canadian

packing shed was using a wax containing the fungicide. The adulterated product was seized in Canada and use of the wax was stopped.

In April 1996, FDA's Minneapolis District Office participated in a meeting with a food firm to discuss the firm's processing of carrots that were grown in North Dakota, shipped to Canada for processing, and imported back into the United States. Import sampling issues were addressed. FDA visited the firm's packing shed and sales office during international visits to Winnipeg in 1993, 1994, and 1995.

During FDA's visits to Canadian officials in Winnipeg, we have also discussed illegal residues/misuse of pesticides with Canada Agriculture and with Health Canada.

Since 1995, members of FDA's Buffalo District Office have met with representatives of CFIA twice per year, primarily to discuss matters of mutual concern regarding problems with food and to maintain effective avenues of communication. We communicate with CFIA several times per year on specific problem entries. For example, when a food entry is made into Canada, found to be violative, and the Canadian importer decides to export to the United States through Buffalo Ports, CFIA advises FDA via electronic mail or by telephone. Upon request, CFIA will fax analytical reports which often serve as the basis for detention. Conversely, FDA routinely advises CFIA when an import entry into the United States has been refused and the lot is destined for exportation into Canada.

Mexico: In 1996 and 1997, FDA participated in the Expoalimentos trade show in Mexico. The Expoalimentos is a conference/exhibition program sponsored by APEX, a food and beverage industry group. The purpose of the event is to promote the exportation of food products from Mexico to the United States. FDA gave a presentation on the import requirements for the United States.

In November 1997, FDA was invited to speak to growers of strawberries and other produce grown in the Mexican State of Guanajuato for export to the United States. FDA discussed Environmental Protection Agency's (EPA) role in regulating pesticides (such as approving use of pesticides and setting tolerances) and FDA's responsibility to monitor domestic and imported food products for pesticide residues. FDA also analyzed, for the Mexican government, samples of fresh fruits and vegetables collected by Mexico.

In March 1997, Andrew and Williamson Sales Company arranged a one-day visit by FDA to Mexico to tour three strawberry farms

under contract with them. The trip was initiated in response to a hepatitis A outbreak that was linked to strawberries that the company purchased from Mexico, processed, and froze.

In May 1997, FDA participated in a meeting sponsored by the Mexican Government to share observations and lessons learned from the hepatitis A outbreak and to discuss emerging issues that affect public health and consumer confidence in food products.

In May 1994, FDA presented a program in Mexico City on the new food labeling regulations and on pesticides.

In October 1993, FDA presented a program in Mexico City on the new food labeling regulations and also discussed exportation of fresh fruits and vegetables to the United States. FDA explained the procedures FDA follows when checking food products as they enter the United States from foreign countries.

Costa Rica: In March 1997, FDA assisted in the analysis of onions that were found to contain residues of the pesticide acephate by the Ministry of Agriculture. Samples of onions were analyzed by FDA, but the presence of acephate could not be confirmed. FDA sent a bilingual chemist to Costa Rica to tour their laboratory and provide technical advice.

Guatemala: In 1996 and 1997, FDA conducted site visits of growing operations and packing sheds in Guatemala in follow-up to epidemiological data that linked the pathogen Cyclospora to raspberries grown in Guatemala.

Central American countries: During June 1995, FDA hosted a training event for Central American pesticide laboratories. Eleven pesticide residue analysts representing five Central American government laboratories were given extensive lecture and laboratory training during these three weeks. The foreign students trained were expected to teach this course to other residue analysts in their home countries using the training manual provided.

6(e) Under the Administration's new initiative, how many new inspectors would be added to the current inspection force? How frequently will FDA inspect foreign growers?

The President's Fresh Produce Initiative was announced in October 1997. The Agency is working with the Administration to determine the number of additional inspectors and other staff needed to implement the initiative beginning in FY99. These

figures will be available when the President transmits the FY99 budget to the Congress.

The October 2, 1997, Presidential directive to the Secretaries of Health and Human Services and Agriculture instructs FDA to develop voluntary guidelines for improving agricultural and manufacturing practices used by the domestic and foreign industry and to monitor and help to improve agricultural practices where problems arise. The primary emphasis of work under the Initiative will be to provide the best guidance possible and to develop intervention and prevention strategies to reduce the occurrence of microbial contamination that may cause human illness. Efforts to improve agricultural practices will focus largely on developing voluntary GAPs and GMPs guidance and facilitating their adoption by engaging in education and technical assistance outreach efforts to the domestic and foreign produce farm communities.

FDA does not envision visiting farms, either domestic or foreign, on a routine basis but will do so on an as-needed basis. The primary focus will be to work with foreign officials to conduct a comprehensive assessment of growing and handling areas. This assessment will allow FDA to assist foreign governments in evaluating the current agricultural practices being followed by their industries and to provide the best guidance and intervention strategies, guided by research and risk assessment, to prevent the occurrence of microbial contamination that may cause human illness. Where necessary, the Agency will visit farms, processors, and/or other exporters within the traceback chain to identify sources of foodborne contamination.

If allocated, the additional resources will also be used to develop the capability to assess more rapidly and accurately the risks associated with microbial contaminants on produce and to develop technologies and testing capabilities required to detect more rapidly and to prevent more effectively, potentially hazardous contamination of these products. The work of the Interagency Risk Assessment Consortium formed in support of the Food Safety Initiative will play a critical role in developing improved microbial risk assessment techniques applicable to produce, establishing priorities for research and education needs, and targeting inspection and other resources to the most pressing hazards associated with fresh fruits and vegetables.

Activities under the Produce Initiative apply equally to domestic and foreign producers. In order to achieve maximum efficiency and effectiveness in the implementation of activities to increase the safety of fresh produce, FDA will

work cooperatively and collaboratively with other Federal agencies, state governments, foreign governments, and all facets of the regulated industry. In the United States, FDA expects to develop partnerships with United States Department of Agriculture (USDA), states, and industry to assist in this effort. In foreign countries, FDA expects to work with foreign governments, United States government counterparts located abroad such as the United States Department of State, the Foreign Agriculture Service and the Animal and Plant Health Inspection Service of USDA, trade associations, and international organizations such as the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations.

7. According to the Administration's description of its new food safety initiative, "[t]he President will send legislation to Congress that will require the FDA to halt imports of fruits, vegetables and other food products from any foreign country with food safety systems and standards that are not on par with those of the United States." Under this policy, does the FDA expect to halt imports from any country which does not inspect to ensure that government established standards are enforced with regard to the processes used to produce fruits, vegetables, and other food products, as well as the products themselves?

H.R. 3052, if enacted, would deem adulterated an imported food that had not been prepared, packed, and held under a system or conditions, or subject to measures, that meet the requirements of the FDC Act or that otherwise achieve the level of protection required for such food prepared, packed, or held in the United States. Just as under the current FDC Act where adulterated domestic food is subject to seizure and condemnation, imported food that appears to be adulterated may also be refused entry.

Under the proposed legislation, a food could be refused entry from a country in which the Secretary has determined that the systems, conditions, and measures applicable to such food products do not achieve the level of protection provided by the systems, conditions, and measures of the United States. Thus, like current law applicable to domestic product, the proposed legislation considers the circumstances (of which inspection would be one aspect) in which an imported food has been prepared, packed, and held, as well as the status of the food itself, in determining whether the food is lawful.

8. On February 18, 1993, the General Accounting Office (GAO) gave important testimony on the use of pesticides on fresh fruits and vegetables that were grown in Mexico and

imported into the United States (copy of testimony is attached). That testimony was given before the Commerce Committee's Subcommittee on Commerce, Consumer Protection, and Competitiveness which was chaired by former Congresswoman Cardiss Collins of Illinois. GAO raised a number of concerns in that testimony, and I have a number of questions that I would like FDA to answer concerning issues raised by GAO.

8(a) With regard to Mexico's regulation of pesticide use on fresh fruits and vegetables, GAO had the following to say in its testimony, "The principal limitation of the Mexican monitoring system is that the government does no monitoring itself ... Instead, the private sector -- Mexican and multinational companies and state and national agricultural growers' associations -- has assumed responsibility for monitoring exports. Companies and associations will test their food only as needed." [emphasis added]. **Is the GAO's characterization of the situation in Mexico still accurate? If so, would the fact that the Mexican government, unlike the United States government fails to do any monitoring itself mean that fruit and vegetable imports from Mexico could be halted by the FDA under the Administration's new food safety policy, since Mexico's food safety systems and standards "are not on par" with those of the United States?**

The GAO characterization does not reflect the current situation. The Government of Mexico now has a program to monitor pesticide residues in agricultural products. This program was established to handle perishable products that have been shown to result in the highest proportion of violative shipments entering the United States.

From the detention information that FDA provides to Mexican officials, problem commodities and their origins are identified, and the determination is made as to which products should be sampled for analysis by the Mexican laboratories. Using these pesticide monitoring results, procedures have been established and corrective actions directed towards farmers and pesticide distributors to promote good agricultural practice and pesticide application. Outreach programs also distribute informational materials and posters to farmers to promote authorized pesticide usage. Additionally, in 1997, a joint program between FDA and the Government of Mexico was established to analyze pre-harvest samples of produce destined for the United States. Under this program, both FDA and Mexican laboratories analyze these samples. Currently, FDA is

analyzing 50 pre-harvest produce samples collected by Mexican inspectors.

In addition to the Mexican pesticide residue monitoring program, some agricultural export associations have their own monitoring program to assure that their products are in compliance with United States requirements. The monitoring programs of the government and the agricultural export associations have different objectives. The government's objective is to determine where a problem originated and to establish preventive and corrective measures. The export association's objective is to assure that the products are in compliance with the residue guidelines established by the importing country.

With regard to the President's Fresh Produce Initiative and its implications for imports from Mexico, the proposed legislation states that a food product could be refused entry from a country in which the Secretary has determined that the systems, conditions, and measures applicable to such food products do not achieve the level of protection provided by the systems, conditions, and measures of the United States. Thus, under H.R. 3052, foods imported from Mexico would be deemed adulterated if the Secretary evaluated the various safeguards of the regulatory scheme (of which inspection would be one aspect) of the Government of Mexico and determined that those safeguards did not achieve the level of protection provided for such food by the United States regulatory system.

8(b) The 1993 GAO testimony, stated: "Mexico has no government agency responsible for enforcing and monitoring pesticide residues." Is this statement still true?

No, this statement is no longer accurate. Mexico has two agencies that share responsibility for monitoring pesticide residues and enforcing applicable standards: the Secretaria de Agricultura, Ganaderia y Desarrollo Rural (SAGAR) is responsible for the usage and application of pesticides in the fields, and the Secretaria de Salud (SSA) assures the safety of the food supply.

8(c) GAO said in its testimony that the Mexican government is establishing a national laboratory system to test pesticide residue levels. At the time of GAO's testimony, Mexico had 5 functioning laboratories to test pesticide residue levels and had plans to add 6 more labs. One of the 5 labs that was functioning at the time of the testimony was owned by the Mexican government and that government-owned lab set the

standards for the other labs in the system. Does FDA have any information concerning the number of labs currently operating in Mexico and Mexico's plans to establish additional labs?

At this time, there are two government laboratories that conduct pesticide residue analyses--one in Mexico City (SSA) and the other one in Matamoros, Tampaulipas (SAGAR). In 1991, the Mexican Government had five laboratories performing pesticide residue analyses. These five laboratories were either closed or transferred to the growers or to agricultural institutions.

Currently, there is one private laboratory officially recognized by the government to perform pesticide residue analyses. There are two additional laboratories undergoing the accreditation process.

8(d) The GAO testimony also reported "a long-term trend whereby importers were disregarding U.S. laws prohibiting the distribution of adulterated foods." The GAO testimony stated, "We found that one-third of the adulterated shipments detected by FDA were not returned for destruction or export and presumably reached U.S. grocery shelves. This problem existed because some importers who were repeatedly caught with adulterated foods chose to pay the relatively low damages assessed by the U.S. Customs Service rather than destroy or return the food."

8(d)(i) What is the percentage of adulterated shipments of imported fruits and vegetables detected by FDA that were not returned for destruction or export in each of the last 4 years?

FDA cannot calculate the percentage of shipments of adulterated imported fruits and vegetables that were not returned for destruction or export in each of the last 4 years because FDA's traditional import data base (the Import Detention System - IDS) was designed to track only detention of imported merchandise but not its ultimate disposition. The Operational and Administrative System for Import Support (OASIS), which became fully operational in December 1997, does permit the tracking of violative shipments from time of entry to final release or refusal, including, in the case of refusal, the ultimate disposition of the refused merchandise. However, under current law, the importer is permitted up to 90 days to make a decision on the final disposition of refused goods, i.e., destruction, export, etc. In addition, there are time lags between FDA's official notification of final shipment disposition and data entry into the data base. For these

reasons, there is, at the present time, no comprehensive information in OASIS (e.g., one year's experience) on the final disposition of shipments of adulterated imported fruits and vegetables.

8(d)(ii) Does the FDA agree with the GAO that adulterated produce is not destroyed or returned, partly because the penalties for failure to destroy or return a shipment are too low?

FDA agrees with GAO's view that inadequate penalties may explain why some adulterated goods are not returned or destroyed.

8(d)(iii) GAO refers to "importers who were repeatedly caught with adulterated foods." How many such "repeat offenders" are there and what actions has the FDA taken to prevent such repeat offenders from continuing to bring adulterated produce into the United States?

FDA's IDS was not designed to identify and monitor firms that repeatedly import adulterated produce into the United States. Therefore, we cannot at this time estimate how many firms are "repeat offenders." OASIS will be able to provide this information. FDA does track regulatory actions taken against firms identified as "problem importers"; however, that description is not limited solely to firms responsible for the distribution of adulterated products that have been refused admission into the United States. FDA has taken regulatory action, including seizure, prosecution, and placement of an importer's product on Detention Without Physical Examination, when evidence demonstrated that the importer failed to meet its obligations with regard to the product being offered for import. The Agency can provide a list of representative regulatory actions if that would be useful to you.

8(e) The testimony stated that "Agricultural imports from Mexico account for nearly one-half of all the fresh and frozen fruits and vegetables exported to the United States from all countries." What are the top ten countries that export fruits and vegetables to the United States? What percentage of total imports of fruits and vegetables is attributable to each of these countries? What percentage of total U.S. consumption of fruits and vegetables is attributable to each of these countries?

The top exporters of fruits and vegetables to the

United States are identified in USDA's Economic Research Service (ERS) report "U.S. Agricultural Imports, Fiscal Years 1996-97." Attachment 1 is a copy of this report. According to ERS data, which is summarized in a special article entitled "Import Penetration in the U.S. Fruit and Vegetable Industry," the United States imported approximately 12-13% (based on millions of pounds) of the vegetables consumed in 1996. Attachment 2 is a copy of this article.

The United States received more than half of all vegetable and melon imports from Mexico, with the majority being fresh-market products and frozen products a distant second. Canada is the second leading foreign supplier of vegetables, with about 15% of the United States import value. Because of the obvious transportation advantages, Mexico and Canada have historically been the top two suppliers of vegetables. The other top suppliers of fresh vegetables to the United States are China -- 5%, the Netherlands -- 4%, and Costa Rica -- 3%.

Imports of fresh fruit rose from 34.7% of fresh domestic consumption in 1990 to 38.3% in 1996. About 10 billion pounds of fresh fruit were imported in 1996, 3 billion pounds excluding bananas. Costa Rica, Ecuador, Honduras, and Colombia are the major suppliers of bananas to the United States market and are the major sources of fruit imports (excluding juices). Excluding bananas, imports rose from 11.6% to 14.9% in 1996 with Chile providing about 23% of imported fruit. Other major sources include Mexico -- 13%, Costa Rica -- 8%, Thailand -- 7%, and Canada -- 7%.

8(f) GAO's testimony stated that, "FDA's testing shows that the Mexican violation rate is generally higher than the violation rate for domestic produce?' [i.e., for pesticide residues on produce]. What has been the violation rate for Mexican grown produce in each of the last 4 years, and how does it compare with the violation rate for U.S. grown produce in each of those years?

The violation rate for domestic and imported produce for the last four years is shown below. While the violation rate for Mexican produce has been higher than violation rates for domestic produce, the violation rate has decreased (4.7% to 3.0%). The violation rate for Mexican produce is now comparable to the total violation rate for all imported produce (see table below). The improvement in compliance of Mexican produce from that of the 1980s is a direct result of a concerted effort by both the Mexican and United States governments to address the issue of pesticide usage in Mexico.

Most of the pesticide residue violations associated with Mexican produce are not due to high levels of pesticides or to residues of "banned" pesticides such as DDT. Instead, as is the case with most pesticide residue violations in produce from other countries and with violations found in domestic produce, the majority of illegal residues on Mexican produce are due to low level residues of pesticides which can be used in the United States on some commodities, but not on the particular commodity on which it was found. Nonetheless, the residues are illegal, and FDA takes appropriate enforcement action when violations are found.

Violation Rate (surveillance data)

Fiscal Year	Domestic Produce	All Imported Produce	Mexican Produce
1993	1.1%	3.3%	4.7%
1994	1.0%	3.5%	5.0%
1995	1.3%	3.2%	3.9%
1996	0.9%	2.6%	3.0%

8(g) GAO's testimony stated that a working group of U.S. (FDA) and Mexican officials was established in 1991 for the purpose of resolving differences in pesticide tolerances, or standards, between Mexico and the United States. These pesticide tolerance differences fall into three groups. In the first group, there are 58 food-use pesticides which have tolerances in both countries, but not for the same commodities. In the second group, GAO found 17 pesticides that have food-use tolerances in Mexico but none in the United States. The third group includes pesticides that have tolerances in both countries for the same commodities but at different levels.

GAO's testimony stated that "the resolution of tolerance differences is critically important...While the working group has set broad priorities for the types of differences to address first, it does not have a long-term those in the third category, and those new tolerances that will occur or be canceled because of continuing changes in the universe of pesticides. Thus, unless the working group addresses all of the differences, it is unlikely that

resolution will be reached for all pesticide tolerances between the United States and Mexico."

8(g)(i) Does the U.S.-Mexico working group on pesticide tolerances still exist? Who are its members? How many times has it met in each of the last 4 years? When is its next meeting scheduled? For how many of the pesticides in the first group and second group has the working group resolved differences between the United States and Mexico as to tolerance levels and the commodities to which they may apply?

Prior to 1995, EPA/FDA worked on a bilateral basis with the Government of Mexico under a consortium of Mexican government agencies known as CICOPLAFEST (Comision Intersecretarial para el Control del Proceso y Uso de Plaguicidas, Fertilzantes y Substancias Toxicas). CICOPLAFEST is comprised of representatives of the Mexican Ministries of Health, Agriculture, Commerce, and Environment. The bilateral activities related to pesticides were intended to identify and address, as necessary, differences between EPA pesticide residue tolerances and Mexican maximum residue limits.

With the formal establishment of the North American Free Trade Agreement Technical Working Group on Pesticides (NAFTA TWG), the bilateral activities between EPA/FDA and CICOPLAFEST were transferred to the NAFTA TWG where they are now being addressed.

The NAFTA TWG is headed by United States, Mexican, and Canadian Co-chairs. The United States chair is held by EPA. FDA and USDA representatives also participate along with representatives from government counterpart organizations in Mexico and Canada. NAFTA TWG meets annually. Subgroups of NAFTA TWG have been formed to address issues related to harmonization of pesticide registrations and tolerances, etc., among the three NAFTA countries. These subgroups meet periodically throughout the year on various projects associated with the harmonization activities. Attachment 3 is a copy of the most recent Progress Report of the NAFTA TWG.

In addition to formal participation by government officials, NAFTA TWG solicits input on pesticide issues from consumer and industry representatives through public meetings which are held annually in conjunction with TWG meetings.

8(g)(ii) Has the working group established a long-term strategy for resolving all differences in U.S. and Mexican tolerances? If so, over what time period are all such differences to be resolved? What progress has been achieved so far in resolving tolerance differences?

The NAFTA TWG on Pesticides has initiated activities to address a variety of issues relating to imports of fresh fruits and vegetables. A report of the progress of the technical subcommittees relating to these issues, including tolerance issues, is contained in the NAFTA TWG on Pesticides Progress Report referenced above.

8(g)(iii) Have working groups been established to resolve similar differences between the U.S. and other major produce exporting countries? If so, what are the countries with which working groups have been established and what is the status of their work?

Except for the activities of the NAFTA TWG, EPA and FDA do not currently have country-specific tolerance harmonization activities underway with other countries. However, the agencies are working on pesticide residue harmonization activities within the framework of international organizations.

The United States participates actively in the Codex Alimentarius Commission's (Codex) Committee on Pesticide Residues (CCPR). An EPA employee is the United States delegate to CCPR. EPA, FDA, and USDA technical experts are members of the United States delegation. The CCPR is charged with developing Maximum Residue Limits (MRLs) for pesticide residues on foods moving in international commerce.

Pesticide residue MRLs recommended by CCPR and adopted by Codex may be considered, in a broad sense, to represent "international tolerances." However, Codex pesticide residue MRLs are not always the same as United States pesticide residue tolerances and currently, the United States does not use Codex MRLs to determine the acceptability of foods offered for import into the country. FDA enforces pesticide tolerances established by EPA and any residue which is not in compliance with an EPA tolerance is illegal, regardless of whether a Codex MRL exists for that commodity.

MRLs adopted by Codex may, in the future, be more consistent with tolerances established by EPA because of two factors. First, the 1996 Food Quality Protection Act (FQPA) requires EPA to consider any existing Codex pesticide MRL whenever the Agency develops or revises a pesticide residue tolerance. Second, CCPR is standardizing the data requirements for its elaboration and adoption of MRLs. These requirements, once final, will bring the international data requirements more in line with domestic United States requirements and may result in a trend toward setting MRLs which are more consistent with EPA tolerances.

While the NAFTA Pesticide TWG is working to harmonize pesticide registrations and tolerances/MRLs in North America, the United States is looking to Codex to develop and support a more systematic approach to harmonization of residue standards at the international level.

8(g)(iv) Does the FDA agree with the GAO that resolving tolerance differences is "critically important" to protecting the safety of produce imported into the U.S.?

No, FDA does not agree with that assessment. Please see our response to question 12 (a).

8(h) The GAO testimony stated that about 1 percent of imported produce shipments were being sampled each year by FDA inspectors. Has the percentage of produce imports sampled by FDA declined, remained the same, or has it increased since 1993? How many visual inspections of imported fruits and vegetables has FDA conducted in each of the last 6 years, and how many laboratory tests on imported produce shipments were conducted in each of the last 6 years?

Since 1993, there has been an overall reduction in the number of shipments of fresh fruits and vegetables from Mexico and other countries sampled by FDA for the purpose of determining compliance with U.S. pesticide residue tolerances. With the generally low violation rates associated with pesticide residues in domestic and imported commodities, FDA redirected its efforts to more pressing food safety issues.

IMPORTED FRESH FRUITS AND VEGETABLES SAMPLED/FIELD EXAMINED FROM FY92 THROUGH FY97**

YEAR	SAMPLES ANALYZED	FIELD EXAMINATIONS	TOTALS
FY92	6,299	6,981	13,280
FY93	4,359	4,628	8,987
FY94	3,804	1,941	5,745
FY95	3,558	2,561	6,119
FY96	3,353	925	4,278
FY97	3,215	907	4,122

**(PODS system data)

8(i) In 1993, there were 13 FDA inspectors at the two primary entry points into the United States for Mexican fruit and vegetable exports---Dallas, Texas, and Los Angeles, California. How many FDA inspectors have there been at the Dallas and Los Angeles entry points to inspect imported produce in each of the last 5 years?

Los Angeles District

YEAR	OTAY MESA	CALEXICO	SAN LUIS	NOGALES[b]	TOTAL
1993	5[a]	1	1	2	9
1994	4	1	1	2	8
1995	4[c]	1	1	3	9
1996	5	1	1	3	10
1997	6	2	1	4	13

[a] includes one individual who transferred to San Francisco in the first quarter of the calendar year and another who retired prior to the end of the year. In addition, there has been a permanent supervisor at Otay Mesa since 1993, who is not included in the numbers.

[b] includes one seasonal employee who retired in the third quarter of the calendar year, 1997.

[c] In addition, beginning in 1995, one employee in Otay Mesa has been used exclusively for EEPS/OASIS implementation and oversight (i.e. filer evaluations, broker training, etc.)

Dallas District

YEAR	EL PASO[1]	LAREDO[2]	LOS INDIOS[3]	PHARR[4]	TOTAL
1993	1	2	-	2	5
1994	2	3	1	1	7
1995	2	3	1	1	7
1996	3	3	1	1	8
1997	3	2	2	2	9

[1] This resident post is responsible for the following ports of entry: El Paso, TX, Columbus, NM, and Santa Teresa, NM;

[2] This resident post is responsible for the following ports of entry: Laredo, TX, Eagle Pass, TX, and Del Rio, TX;

[3] This resident post is currently responsible for the following ports of entry: Los Indios, TX, Brownsville, TX, and Progresso, TX. In 1993, these ports of entry were the responsibility of other resident posts;

[4] This resident post is responsible for the following ports of entry: Pharr, TX, Rio Grande City, TX and Roma, TX.

8(j) The GAO testimony stated that "FDA relied on analytical test methods which can detect less than half of the pesticides potentially available in world markets." Is this statement still true, or is the FDA able to detect a larger number of the pesticides potentially available today than was the case in 1993?

The GAO statement, which refers to multiresidue methods, is still basically correct in that FDA currently has six multiresidue methods (MRMs) that can determine about half of

the approximately 400 pesticides with EPA tolerances, and many others that have no established tolerances. To analyze the large number of samples whose pesticide treatment history is usually unknown, FDA generally uses analytical methods capable of simultaneously determining a number of pesticide residues.

In addition to the MRMs, the Agency does have single residue methods or selective MRMs that can be used to determine other pesticides not covered by an MRM, thereby extending FDA analytical capabilities. These types of methods are, however, usually more resource-intensive per residue, may require at least as much time to perform as an MRM, and are much less cost efficient than MRMs. FDA continues to monitor pesticide usage through the development of new analytical methods and the use of targeted monitoring of specific pesticides, commodities, and countries through foreign pesticide usage and registration information. Targeted monitoring is also directed to domestically produced foods.

8(k) The GAO testimony also stated that "FDA was limited in its ability to better target testing because it lacked knowledge about which pesticides were being used in foreign countries." What has the FDA done to increase its knowledge of pesticides being used in foreign countries? Does the FDA believe its enforcement efforts would be enhanced if produce imported into the U.S. were required to be labeled identifying the pesticides with which the produce has been treated?

From 1987 through 1995, FDA acquired foreign pesticide usage data from commercial sources and through bilateral cooperation with the governments of several food exporting countries. This activity was mandated by the 1988 Pesticide Monitoring Improvements Act. Pesticide usage data acquired from these sources has, to some extent, assisted the Agency in directing pesticide residue monitoring toward those pesticides most likely to have been used on imported commodities, thereby enabling the Agency to increase its effectiveness in the monitoring of imported foods for residues of selected pesticides.

Commercial foreign pesticide usage data is expensive, costing in the range of $320,000 per year. In light of FDA's limited resources and the fact that pesticide usage patterns are generally consistent over several years, the Agency elected to discontinue purchase of new foreign pesticide usage data. Nonetheless, the existing information on hand is sufficient to guide FDA's pesticide residue monitoring program for several more years.

With regard to the question of labeling of imported foods with information about pesticide treatment history, several legislative proposals in the late 1980s and early 1990s included such language. This legislation would have required labeling for pesticides "known to be or customarily used on, or in connection with the production of, food by any agricultural producer or group of agricultural producers of the food." FDA believes that such a requirement would be logistically unworkable and would be viewed by the governments of exporting countries as a non-tariff trade barrier if similar labeling were not required for domestic foods.

The suggestion of such labeling also assumes that it is feasible for a foreign producer or United States importer to determine accurately through growers in the country of origin which pesticides have been or may have been used on the particular commodity during its cultivation. Accurate pesticide usage data, even that tabulated on a national rather than local level, is extremely difficult and expensive to obtain. Co-mingling of production lots during the various stages of production and shipment make accurate statements about pesticide usage on a particular shipment virtually impossible.

9. The 1993 GAO testimony stated, "Since the Mexican government does not monitor residue levels for exported produce, U.S. inspections are all the more important." Has the FDA increased its inspections at the border or in Mexico since 1993?

FDA does not routinely assign inspectors to inspect and monitor growers in foreign countries. As mentioned in the responses to other questions, however, FDA has sent personnel to foreign countries in response to specific incidents to obtain information and to provide technical assistance.

Since 1993, FDA's field data show that the total number of fresh fruit and vegetable samples from Mexico that have been analyzed or examined at the border has declined. (See table below).

IMPORTED FRESH FRUITS AND VEGETABLES FROM MEXICO SAMPLED/ FIELD EXAMINED FROM FY93 THROUGH FY97**

YEAR:	SAMPLES ANALYZED	FIELD EXAMINATIONS	TOTALS
FY93	1,620	4,227	5,847
FY94	1,394	500	1,894
FY95	1,627	1,278	2,905
FY96	1,577	485	2,062
FY97	1,500	529	2,029

**(PODS data)

10. For each year since the North American Free Trade Agreement (NAFTA) went into effect, please report:

10(a) the number of inspections of imported Mexican fruits and vegetables that the FDA has conducted to determine compliance with U.S. pesticide and other requirements:

Please see above table.

10(b) the number of violations that these inspections have identified; and

The NAFTA agreement was signed on December 17, 1992. The violations of Mexican produce (detention based upon sample analysis) for FY93 through FY97 are as follows:

YEAR	VIOLATIONS
FY93	227
FY94	216
FY95	231
FY96	140
FY97	57

10(c) the number of inspections and violations FDA conducted in each of the 5 years prior to NAFTA's taking effect.

IMPORTED FRESH FRUITS AND VEGETABLES SAMPLED/
FIELD EXAMINED FROM FY88 THROUGH FY92**

YEAR	SAMPLES ANALYZED	FIELD EXAMS
FY92	6,299	6,981
FY91	7,257	4,523
FY90	7,238	2,703
FY89	9,510	31,505
FY88	7,663	833

YEAR	VIOLATIONS
FY92	593
FY91	405
FY90	615
FY89	787
FY88	1,779

**(PODS data)

12(b) How would the FDA describe its limitations in providing protection against public exposure to prohibited pesticide residues on imported foods?

As stated in our response to question 12 (a), we believe that the Agency's efforts directed at monitoring fresh produce for pesticide contamination provide adequate public health protection.

It is true that FDA resources are limited. The May 1997 Report to the President, "Food Safety from Farm to Table," noted that today, FDA is responsible for about 2.2 million import food entries (i.e., shipments), an increase from 1.5 million entries just 5 years ago, with the same number of staff. Given relatively fixed resources for the review, examination, and sampling of imported foods, FDA has been addressing the increasing volume of import food entries through computerization and targeting of "high risk" products.

Other limitations have been described in the answers to questions 5(b) and 8(d)(ii).